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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,737	09/29/2003	Lisa Donnelly	MIT-5021	1928
27777	7590	12/31/2007		
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			EXAMINER COMSTOCK, DAVID C	
			ART UNIT	PAPER NUMBER
			3733	
			MAIL DATE	DELIVERY MODE
			12/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/673,737

Applicant(s)

DONNELLY ET AL.

Examiner

David Comstock

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Rule 132 Declaration

The declaration under 37 CFR 1.132 filed 01 October 2007 has been fully considered but is insufficient to overcome the outstanding rejection for the following reasons.

While the declaration works in favor of nonobviousness, it does not outweigh the basic fact that selecting known materials based on their suitability for the intended use is a matter of obvious design choice. Even if some routine experimentation was necessary, it is noted that a person of ordinary skill in the art is not an automaton, but rather, is a person of ordinary ingenuity, and as such, could be presumed to be capable of selecting and/or combining known materials as described. That declarant was aware of an article standing for the proposition therein does not in any way prove that others were aware of a long-felt need. Moreover, the suggestion that an issued US Patent (5,632,748) is inoperable or did not already satisfy any long-felt need is not persuasive in view of the presumption of validity to which issued patents are entitled. Much weightier evidence would be necessary to overcome this presumption of validity. Finally, it has been noted that the declarant shares an interest in the outcome of this application. While this is in no way improper, it must be taken into account in weighing the evidence. Accordingly, for these reasons the declaration does not overcome the outstanding rejection set forth below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11, as best understood, are rejected under 35 U.S.C. 103(a) as being unpatentable over Beck, Jr. et al. (5,632,748).

Beck, Jr. et al. disclose providing a graft 16 in bone tunnels 10 formed in the femur 10 and tibia. See, e.g., Fig. 1 and col. 6, line 24 - col. 7, line 24 and col. 15, lines 45-51. The grafts are secured in the tunnels by an interference screw 28 that may be formed of biodegradable materials (*id.*). The tunnels are tapped by the self-tapping threads of the device. See, e.g., Fig. 1 and col. 7, lines 35-62. Beck, Jr. et al. do not explicitly recite the biodegradable material comprising a copolymer of polylactic or polyglycolic acid and a bioceramic such as TCP or other calcium phosphates, hydroxyapatite, calcium sulfates, calcium oxides, calcium carbonates, and magnesium phosphates. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the device of a biodegradable material comprising a copolymer of polylactic or polyglycolic acid and a bioceramic such as TCP or other calcium phosphates, hydroxyapatite, calcium sulfates, calcium oxides, calcium carbonates, and magnesium phosphates, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. It

also would have been obvious to provide the copolymer of polylactic or polyglycolic acid in an amount comprising about 85 mole percent to about 95 mole percent of polylactic acid and about 5 mole percent to about 15 mole percent of polyglycolic acid; and to provide the bioceramic in an amount of about 2.0 volume percent to about 25.0 volume percent of bioceramic, or about 15.0 volume percent, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Response to Arguments

Applicant's outstanding arguments have been fully considered but are not persuasive.

The declaration under 37 CFR 1.132 and corresponding arguments are not persuasive for the reasons set forth above in the discussion pertaining the Rule 132 Declaration.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-4710. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. Comstock



EDUARDO A. ROBERT
SUPERVISING EXAMINER